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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/887,505	07/02/1997	ROBERT L. KILKUSKIE	HYZ-040CIP	1117

7590

04/20/2006

HALE AND DORR
60 STATE STREET
BOSTON, MA 02109

EXAMINER

MARTINELL, JAMES

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/887,505

Applicant(s)

KILKUSKIE ET AL.

Examiner

James Martinell

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-13, 15-31 and 42-52 is/are pending in the application.
- 4a) Of the above claim(s) 7, 23, 24, 26, 29, 31, 44, 46 and 50 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21, 42 and 49 is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 10-13, 15-20, 22, 25, 27, 28, 30, 43, 45, 47, 48, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 1997 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1634

Applicants' comments in connection with the requirement for restriction are noted. No determination, explicit or implicit, is made by the USPTO that it would not be an undue burden to search all of the sequences mentioned in the instant claims. There was no election of species requirement in the requirement for restriction mailed April 29, 2005, so any and all of applicants' comments regarding election of species practice are not relevant. Applicants' assertion that "If the Examiner indeed meant 'election' of species, then Applicants respectfully aver that they are entitled to the examination of additional species upon the allowance of the elected species." (response filed January 20, 2006, page 11) is inexplicable in view of the statement in the Office action mailed April 29, 2005 at page 2 that, "This requirement for election of SEQ ID NOs is not a requirement for an election of species, but a requirement for election of a single invention." In view of applicants' request for clarification, the examiner cannot improve upon what was stated in the April 29, 2005 Office action. Applicants also assert that they were and are entitled to select ten combinations of sequences for claims 42-45. This is an incorrect notion. The Office action of April 29, 2005 at page 2 among other things, states, "Claims 42-45 are drawn to compositions reciting different combinations of individual nucleotide sequences. Applicant is required to select one combination for examination." Applicants are incorrect in asserting that they were entitled to select ten combinations of sequences.

The requirement for restriction is deemed proper and is here made FINAL.

Claims 7, 23, 24, 26, 29, 31, and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 19, 2005 and again in the response filed January 20, 2006.

Newly submitted claims 44 and 50 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the instant claims embrace more than was elected.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Art Unit: 1634

Accordingly, claims 44 and 50 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed October 20, 2005, page 3, item (a)). The recitation of "synthetic oligonucleotide" (claim 43) is vague and indefinite because the instant application does not distinguish between synthetic and non-synthetic oligonucleotides. Applicants may have intended to amend claim 43 similarly to the amendments made in claims 1, 2, 4, 5, and 8 in the response filed January 20, 2006.

Claims 2-6, 8, 10-13, 15-20, 25, 27, 28, 30, 43, 45, 47, and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed October 20, 2005, page 3). In *Vas-Cath v Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991) the court stated, "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (emphasis in the original) (*Vas-Cath* at page 1117). The instant application does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now claimed" (*Vas-Cath* at page 1116). In *Fiers v. Sugano*, 25 USPQ2d 1601 (Fed. Cir. 1993), the court also held that, "An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference a potential method for isolating it; what is required is a description of the DNA itself" (*Fiers v. Sugano*, page 1606). This view was reiterated in *Fiddes v. Baird*, USPQ2d 1481 (BPAI 1993) at page 1483, "If a conception of a DNA requires a specific

Art Unit: 1634

definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. . . . one cannot describe what one has not conceived."

The court amplified this notion with respect to inventions claiming genetic material in *Regents of the University of California v. Eli Lilly*, 43 USPQ2d 1398 (Fed. Cir. 1997), stating at page 1406,

"In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. . . . Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material."

Thus, applicants' arguments in connection with the functional properties of the claimed oligonucleotides (response filed January 20, 2006, pages 14-16) are not convincing.

Claims 2-6, 8, 10-13, 15-20, 25, 27, 28, 30, 43, 45, 47, and 48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 38, does not reasonably provide enablement for all of the claimed combinations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed October 20, 2005, page 4, first full paragraph). The discussion in the previous rejection hereinabove is incorporated here.

Claims 2, 6, 8, 10-12, 22, 45, 47, and 52 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Anderson et al (WO 94/05813 (March 17, 1994)). This rejection is repeated for reasons already of record (*e.g.*, Office action mailed October 20, 2005, page 4). Applicants' arguments (response filed January 20, 2006, page 18) is most unconvincing. First, the reference clearly embraces the use of ribonucleic acids (*e.g.*, see page 8, second full paragraph). Second, applicants' argue that the sequence in Anderson et al is not the same as that in SEQ ID NO: 8, pointing to Ts in the reference as opposed to

Art Unit: 1634

Us in SEQ ID NO: 38. It is well known that U (*i.e.* uracil in RNA is equivalent to T (*i.e.* thymine) in DNA; *e.g.* see MPEP 2422, Table 1. Thus, the sequence of Anderson et al anticipates the claims.

Claims 1, 8, 12, and 51 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sheridan et al (WO 93/13224 (July 8, 1993)). This rejection is repeated for reasons already of record (*e.g.*, Office action mailed April 29, 2005, page 5). Applicants previously avoided this rejection by narrowing the scope of the claims. The amendment to claim filed January 20, 2006 has broadened the claimed subject matter such that the reference applies to the claims.

Claims 21, 42, and 49 are allowable over the prior art of record. The claims are construed to embrace only oligonucleotides that contain the entire sequences mentioned in the claims and not merely portions of any of those SEQ ID NOs mentioned in the claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

Art Unit: 1634

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.


OFFICIAL FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1634

9/14/08